510(k) Summary

Submitter:	Edwards Lifesciences LLC
Submitter Contact:	Luke Meidell, Regulatory Affairs Associate II 12050 Lone Peak Pkwy Draper, UT 84020 Ph - (801) 565-6212 Fax – (801) 565-6108
Date Prepared:	July 19, 2013
Trade Name:	Edwards EMBOL-X™ Introducer Sheath
Classification Name:	Introducer, Catheter, Cardiovascular Devices Panel; 21 CFR §870.1340 Product Code DYB, Class II
Predicate Device:	K002973, EMBOL-X Introducer

JUL 2 4 2013

Device Description:

Edwards Lifesciences' EMBOL-X Introducer Sheath is a sterile, non-pyrogenic, single-use introducer made of flexible and non-flexible polymeric materials. It consists of a single lumen housing and a removable, snap-lock obturator.

The housing has a flexible suture flange for attachment to the vessel and orientation markings on the shaft and suture flange to assist in the placement of the EMBOL-X Introducer Sheath. Inside the housing is an internal valve to prevent backbleeding.

The device also has additional suture loops on the proximal end of the Introducer housing and a design that allows air to vent from the Introducer during insertion.

Intended Use:

Intended as a device access port to the vasculature during cardiovascular surgery.

Indications for Use:

The Indications for Use statement was revised from the predicate device (which allowed introduction of intravascular devices) to only allow introduction of EMBOL-X Intra-Aortic Filters. This revised Indication still falls within the old indication, although it limits the device to use with one intravascular device—the EMBOL-X Intra-Aortic Filter.

> *The EMBOL-X Introducer Sheath is indicated for use in procedures requiring the introduction of EMBOL-X Intra-Aortic Filters.*

Comparative Analysis:

The subject device has the same intended use and technological characteristics (i.e., design, material, chemical composition) as the predicate device. It has been demonstrated that the subject EMBOL-X Introducer Sheath is comparable to the predicate device in fundamental scientific technology, material types, principles of operation, and functional performance evaluations. No new issues of safety or efficacy have been raised.

Functional/Safety Testing:

The functional data indicate that the EMBOL-X Introducer Sheath performs in a substantially equivalent manner when compared to the predicate device. The following functional tests were performed:

- Biocompatibility
    - Cytotoxicity
    - Haemocompatibility
    - Irritation/Intracutaneous Toxicity
    - Sensitization
    - Systemic Toxicity
    - Pyrogenicity
    - Genotoxicity
    - Thrombogenicity
- Sterility
- Performance Testing / Shelf Life
    - Tensile
    - Leak

- Vent
- Latch Compression
- Flange Flex
- Insertion, Removal, and Retention Force
- Functional/Compatibility testing with associated devices

All data met acceptance criteria.

Conclusion:

The Edwards EMBOL-X Introducer Sheath testing confirms that the subject EMBOL-X Introducer Sheath is substantially equivalent to the predicate EMBOL-X Introducer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2013

Edwards Lifesciences LLC
C/O Luke Meidell, Regulatory Affairs Associate II
12050 Lone Peak Pkwy
Draper, UT 84020

Re: K123714
Trade/Device Name: Edwards EMBOL-X™ Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: July 12, 2013
Received: July 15, 2013

Dear Mr. Luke Meidell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123714

Device Name: EMBOL-X Introducer Sheath

Indications for Use:

The EMBOL-X Introducer Sheath is indicated for use in procedures requiring the introduction of EMBOL-X Intra-Aortic Filters.

Prescription Use __x__ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)